

REMARKS

In the Office Action, the Examiner has allowed claim 23, objected to claim 20 and rejected claims 13-19, 21 and 22, and has withdrawn claim 25 from consideration. With this amendment claims 13 and 17 have been amended and claim 25 has been cancelled. The application includes claims 13-23.

In the Office Action, newly submitted claim 25 was withdrawn from consideration alleging that the claim was directed to an invention that is independent or distinct from the invention as originally claimed and that the newly submitted claim was directed to a product while previously presented claims 1-24 were directed to a process of use. Applicant's attorney respectfully disagrees that newly submitted claim 25 is directed to an invention that is independent or distinct from the invention originally claimed. However, to further the prosecution of this case, claim 25 has been cancelled while reserving the right to pursue claim 25 in a divisional application.

The Office Action rejected claim 13 under 35 U.S.C § 102(b) as being anticipated by U.S. Patent No. 5,397,628 ("Crawley et al"). The Office Action alleges that Crawley et al. discloses the claimed invention and particular points to example 3 alleging that example 3 discloses an entire individual patch. The Office Action also states "the applicant should note that the patch is unattached to the knee brace in example 3, unit adhesively secured thereto."

Applicant's attorney believes that it would be worthwhile to discuss certain advantages of the present invention. The invention was developed to provide the user with options to reduce friction when and where excessive friction developed. People vary greatly in their physical makeup and their movement. For example, different shoes, even on the same person, fit and

irritate the skin in different places. The variety of objects that touch and irritate the skin and how such touching and irritation occur is endless. In this context, it is believed that neither of the two cited references (discussed below) teach or suggest the invention as defined in the amended claims.

Independent claim 13 has been amended as suggested by the Office Action to state that the patch is independent of the support object or any other object adjacent the tissue until the patch is adhesively secured. The Crawley et al. patent does not anticipate claim 13 as amended. Applicant's attorney has carefully reviewed example 3, and disagrees with the Office Action that example 3 describes a patch that is unattached to the knee brace until it is adhesively secured thereto. All that example 3 discloses is a section of PTFE film that has an adhesive applied on one side and that the foam rubber has an adhesive applied in a matching area on to which the PTFE film is to be secured.

As amended, in addition, independent claim 13 utilizes a pressure sensitive adhesive. Support for this amendment is found on page 12, lines 25-26 of the present application. The disclosure in the Crawley et al. patent of applying adhesive to both objects describes a process in making a knee brace. In contrast, the present invention as defined in amended claim 13 utilizes a pressure sensitive adhesive which is employed by a user in securing the patch of the present invention to either tissue or to the object that supports the tissue. As amended, independent claim 13 is not anticipated by the Crawley et al. patent, since Crawley et al. does not contain each and every element of independent claim 13. It is respectfully requested that the rejection under 35 U.S.C § 102(b) be withdrawn and claim 13 allowed.

Next, the Examiner rejected claims 14 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Crawley et al. alleging that

although Crawley et al. failed to teach a shoe being the object in the region of the metatarsal-phalangeal joint region, that in column 1, lines 23-28, Crawley et al. disclosed "...in other body portions requiring some support while still allowing some flexibility or movement". The statement in Crawley et al. in column 1, lines 23-28 is speculative. Such a disclosure can not enable a claim that states that the shoe is the object or that the region is the metatarsal-phalangeal joint region. Consequently, it is not seen how such a statement can be used to render an obviousness type rejection. The statement in Crawley et al. in column 1, lines 23-28 provides no enablement for any type of structure. In view of the above, it is believed that claims 14 and 15 are now in allowable form along with the same reasons given for claim 13. Reconsideration and allowance of claims 14 and 15 are respectfully requested.

The Office Action also rejected claims 13, 16, 17, 18, 21 and 22, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 3,732,578 ("Pollack") in view of Crawley et al.

With regard to claims 13 and 16, the Office Action alleges that Pollack discloses a management method for a prosthetic device having a socket receiving portion of a limb to be supported and it's exposed surface loading against the limb having support bones, tissue around the support bones and skin on an outer side of the tissue. However, more interestingly and more important, is the Office Action's statement that Pollack fails to teach ... that the pads have an exposed surface of low friction, and that the pads are adhesively attached to the object or tissue. These two characteristics are in essence applicant's claimed invention.

But somehow, the Office Action finds motivation to combine Crawley et al. with Pollack to come up with a combination that is supposedly applicant's invention. Pollack describes a low density latex foam pad that is employed as a removable insert of

permanent laminate for a prosthetic device and provides a cushion which conforms on one surface to a surface of the socket of the prosthetic device and another surface to the distal segment of a human body member. Crawley et al., on the other hand, describes a support that includes a laminated cellular body knee brace having a PTFE layer. Crawley et al. describes a process of adhesively securing a polyurethane coated porous expanded PTFE film to cellular neoprene rubber. The intent of the Crawley et al. patent is to place the PTFE film on the cellular rubber. There is absolutely no motivation in Crawley et al. to make an individual patch for securance with a pressure sensitive adhesive. Likewise, in Pollack, the pad described is a low density latex foam having a high compression set that provides a cushion to one surface of the socket of the prosthetic device. Applicant's attorney can not find the motivation in Pollack et al. to make the Pollack pad of a low friction material. The purpose of the cushion in Pollack is to determine the location of pressure points so that the prosthetic device can be modified to alleviate discomfort caused by such pressure points. (Col. 1, lines 43-Col. 2, line 12). There is no motivation to make it low friction.

As the MPEP states, "the mere fact that references can be combined or modified does not render the resulting combination obvious unless the prior art also suggests the desirability of the combination. In Ray Mills, 16 U.S.PQ2d 1430 (Fed. Cir. 1990)

It is only after viewing applicant's disclosure that motivation occurs to make an individual low friction pad. All the Office Action describes for more than a page is how one having ordinary skill in the art could modify either the structure in Pollack or the structure in Crawley et al. to meet the claimed invention. This is insufficient to establish a prima-facie case of obviousness. The Office Action provides no objective reason to combine Pollack with Crawley or vice-versa. The only objective

teaching is applicant's disclosure. In view of the above, it is respectfully requested that the rejection under 35 U.S.C. § 103(a) regarding claims 13 and 16 be withdrawn and the claims allowed.

The Office Action then referred to independent claim 17 and stated that Pollack somehow inherently discloses a method of reducing trauma to tissue supported on an object. The Office Action states that Pollack describes the "steps of selecting a plurality of support regions of high load or sheer load on tissues likely to cause damage (this is accomplished by placing a device on the user to determine the high load areas, and provide a separable, individual patch having a peripheral edge defining the patch between each of the plurality of the regions of high load in an object supporting the tissue)."

Applicant's attorney has carefully reviewed the Pollack patent and can not find any motivation for a low friction pad in Pollack's invention. The characteristic that Pollack clearly desires is a low density, nonresilient, deformable cushioning material that exhibits a memory characteristic for enhancing the cushioning effect between a body member and a prosthetic device.

It is true that the pad of Pollack may be used to provide comfort between the body part and the prosthetic device, but only if no pressure points were found, or the pressure points have been corrected. Col. 3, lines 8-24.

Crawley et al., on the other hand, teach use of applying adhesive both to the PTFE film and to the knee brace. As amended, independent claim 17 utilizes a pressure sensitive adhesive. The use of securing adhesives to both the object and to the PTFE film describes a manufacturing process and can not provide motivation for a patch that is secured by an end user. Therefore, in view of the above, it is believed that independent claim 17 is in allowable form and reconsideration and allowance of independent claim 17 are respectfully requested.

With regard to the Office Action's comments about claim 19 and how a mental step can not be a factor in determining patentability, they are not understood. First, such steps as "identifying" are not completely mental in nature. The act of placing the surface patch on a region is within "identifying" and makes this step physical in nature. "Identifying" is a term that is often used in method claims. Method claims may often include one or more steps that are somewhat mental in nature. The Office is requested to provide a rule or case law which states that a "mental step" is not a factor in determining patentability. It is respectfully requested that the rejection of claim 19 be withdrawn and the claim allowed.

With regard to claim 21, the rejection is not understood. Column 3, lines 8-12 in Pollack does not describe an "additional" pad, but a substitute pad after the contour of the interior surface of the socket has been adjusted to relieve the socket of pressure points. Therefore, pad(s) in addition to the pad already used is not disclosed nor is one skilled in the art motivated to add an additional low friction pad. The prosthesis has only the one socket, so how can "additional" pads be added? It is respectfully requested that the rejection of claim 21 be withdrawn and the claim allowed.

Regarding the Examiner's comments that claim 22 does not disclose that the adhesive is permanent, but therefore the patch is inherently removable, applicant disagrees. If anything, Crawley et al. discloses an adhesive that is permanent. Why would a knee brace be made having a layer that is removable. In fact, due to the high friction between a rubber cellular knee brace and the knee, a good bond is required for the PTFE film or the PTFE layer in Crawley et al. will not remain in its original desired location when the knee brace is placed around the knee. It should be appreciated that cellular rubber knee braces are

stretched and pulled into position. Such knee braces function when they are a tight fit. See discussion in Crawley et al column 1, lines 29-42. Subsequently, the bond of Crawley et al. has to be a good permanent bond. Crawley et al. discuss the need for a good bond. See example 4 of Crawley et al. In view of the above, it is respectfully requested that the rejection of claim 22 be withdrawn and the claim allowed.

In view of the above, it is believed that the application is now in condition for allowance, and reconsideration and allowance of all the claims are respectfully requested. The Examiner is requested to give the undersigned attorney a call if any issues can be resolved over the phone.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

WESTMAN, CHAMPLIN & KELLY, P.A.

By: 

Z. Peter Sawicki, Reg. No. 30,214

Suite 1400 - International Centre

900 Second Avenue South

Minneapolis, Minnesota 55402-3319

Direct Dial: (612) 330-0581 / Fax: (612) 339-3312

ZPS:rdrr